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**UNITED STATES DEPARTMENT OF COMMERCE**  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/443,542 11/19/99 RASTINEJAD

F PC10228A

023913  
PFIZER INC  
235 E 42ND STREET  
NEW YORK NY 10017

HM12/0713

EXAMINER

GOLDBERG, J

ART UNIT	PAPER NUMBER
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1614

DATE MAILED:

07/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**09/443,542**

Applicant(s)  
**Rastinejad**

Examiner  
**Jerome D. Goldberg**

Art Unit  
**1614**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jun 4, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above, claim(s) 1-8 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-23 and 25-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 6 & 10 20) ☐ Other:

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The WO patent and the Foster et al. reference are cited to complete the record.

Claims 1-8 and 24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 9.

Applicants elected, the compound X from the Group I-ion-peptide compound and the treatment of cancer.

Claims 9-23 and 25-35 will be examined as they read as the elected invention of compound X for treating cancer.

Claims 9-23 and 25-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific disease condition and/or specific cancers disclosed, does not reasonably provide enablement for the terms "disease state ..." and "cancer". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The terms "disease state..." in claims 9-15 and "cancer" in claims 16-23 and 25-35 lack clear exemplary support in the specification as filed.

The cancer therapy art remains highly unpredictable and no examples exist for efficacy of a single compound against disease state or cancers generally. Therefore, based on the unpredictable nature of the invention and state of the prior art, lack of guidance and working examples, and extreme breadth of the claims, one skilled in this art could not use the entire scope of the claimed invention without undue experimentation. Changing the term "disease state..."

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sensitive to the compound of formula I" and "cancer sensitive to the compound of formula I" would overcome this rejection.

Claims 9-19, 21-23 and 26-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific compounds disclosed, does not reasonably provide enablement for the term "an organic non-peptide compound...". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The term "an organic non-peptide compound..." in claims 9-19, 21-23 and 26-35 lacks clear exemplary support in the specification as filed.

Claims 9-23 and 25-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16, 17 and 26; 18 and 27; 19 and 28; 21 and 29; 22 and 30 and 23 and 31 fail to differ in scope and correction is required. Applicants state in Paper No. 9 that they "will cancel claim 1-25 from the present application". Claims 9-23 and 25-35 fail to recite the amount of the active compound being employed. Without an amount, the amount could be so small as to be meaningless. Correction is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner J. D. Goldberg whose telephone number is (703) 308-

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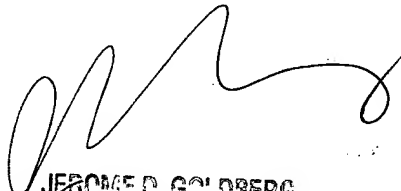
4606. The examiner can normally be reached on Tuesday through Thursday from 9:00 a.m. to 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

J.Goldberg:jmr

June 29, 2001



JEROME D. GOLDBERG  
PRINCIPAL EXAMINER  
GROUP 1200